IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF SOUTH CAROLINA
CHARLESTON DIVISION

EMERY I. FEESER, Plaintiff, vs. MEDTRONIC, INC., Defendant.	)	No. 2:21-cv-03808-DCN **ORDER**

The following matter is before the court on defendant Medtronic Inc.'s ("Medtronic") motion to dismiss, ECF No. 5. For the reasons set forth below, the court grants in part and denies in part the motion.

I. BACKGROUND

On or about July 7, 2018, plaintiff Emery I. Feeser ("Feeser") underwent surgery at Roper Hospital in Charleston, South Carolina to implant a Medtronic pacemaker—the Azure™ S DR MRI SureScan™ Model W3DR01, serial number RNJ201863H (the "Pacemaker"). The Pacemaker is a Class III medical device that received premarket approval ("PMA") from the U.S. Food and Drug Administration ("FDA") in August 2017 to treat multiple heart conditions that require chronic heart rate regulation. Following the procedure, Feeser allegedly started having problems with the Pacemaker, and it stopped working altogether. According to Feeser, the Pacemaker was inadvertently manufactured without its usual protective coating that allegedly reduces the likelihood of a pacemaker being rejected by a recipient. On October 16, 2018, Feeser underwent a second surgery to remove the Pacemaker and replace it with a new Medtronic pacemaker—model DDDR S1, serial number NWA 238501H—with the protective coating.

On October 11, 2021, Feeser filed this action in the Charleston County Court of Common Pleas. ECF No. 1-1, Compl. On November 19, 2021, Medtronic removed the action to this court. ECF No. 1. On November 24, 2021, Medtronic filed a motion to dismiss for failure to state a claim. ECF No. 5. On December 8, 2021, Feeser responded in opposition, ECF No. 7, and on December 15, 2021, Medtronic replied, ECF No. 8. As such, the motion to dismiss has been fully briefed and is now ripe for review.

II. STANDARD

A Federal Rule of Civil Procedure 12(b)(6) motion for failure to state a claim upon which relief can be granted "challenges the legal sufficiency of a complaint." Francis v. Giacomelli, 588 F.3d 186, 192 (4th Cir. 2009) (citations omitted); see also Republican Party of N.C. v. Martin, 980 F.2d 943, 952 (4th Cir. 1992) ("A motion to dismiss under Rule 12(b)(6) . . . does not resolve contests surrounding the facts, the merits of a claim, or the applicability of defenses."). To be legally sufficient, a pleading must contain a "short and plain statement of the claim showing that the pleader is entitled to relief." Fed. R. Civ. P. 8(a)(2). A Rule 12(b)(6) motion should not be granted unless it appears certain that the plaintiff can prove no set of facts that would support his claim and would entitle him to relief. Mylan Labs., Inc. v. Matkari, 7 F.3d 1130, 1134 (4th Cir. 1993). When considering a Rule 12(b)(6) motion, the court should accept all well-pled allegations as true and should view the complaint in a light most favorable to the plaintiff. Ostrzenski v. Seigel, 177 F.3d 245, 251 (4th Cir. 1999); Mylan Labs., Inc., 7 F.3d at 1134. "To survive a motion to dismiss, a complaint must contain sufficient factual matter, accepted as true, to 'state a claim to relief that is plausible on its face.'" Ashcroft v. Iqbal, 556 U.S. 662, 678 (2009) (quoting Bell Atlantic Corp. v.

Twombly, 550 U.S. 544, 570 (2007)). "A claim has facial plausibility when the plaintiff pleads factual content that allows the court to draw the reasonable inference that the defendant is liable for the misconduct alleged." Id.

III. DISCUSSION

Medtronic requests that the court dismiss Feeser's complaint in its entirety for failure to state a claim upon which relief may be granted pursuant to Rule 12(b)(6). Medtronic brings its motion on two grounds. First, Medtronic argues that every claim is preempted by the Medical Device Amendments of 1976 ("MDA") to the Federal Food, Drug, and Cosmetic Act ("FDCA"), 21 U.S.C. § 360k(a). Second, Medtronic argues that Feeser's complaint does not contain sufficient facts to give rise to a plausible claim for relief. The court addresses each argument in turn.

A. Preemption

Medtronic first asks the court to dismiss all of Feeser's claims as preempted by federal law. In 1976, Congress passed the MDA in order to impose detailed federal oversight to govern medical devices. Walker v. Medtronic, Inc., 670 F.3d 569, 572 (4th Cir. 2012). "To that end, the MDA includes a provision expressly preempting state regulation of medical devices." Id. It states in relevant part:

> [N]o State or political subdivision of a State may establish or continue in effect with respect to a device intended for human use any requirement—
> (1) which is different from, or in addition to, any requirement applicable under this chapter to the device, and
> (2) which relates to the safety or effectiveness of the device or to any other matter included in a requirement applicable to the device under this chapter.

21 U.S.C. § 360k(a). "The MDA also establishes three classes of medical devices, organized according to the level of oversight required to ensure their safety." Walker, 670 F.3d at 572. "Class III devices require the highest level of federal oversight," and the

Pacemaker in this case is a Class III device. Id. "Because of the risks associated with them, Class III devices are required to go through [PMA] 'to provide reasonable assurance of [their] safety and effectiveness.'" Id. (quoting 21 U.S.C. § 360c(a)(1)(C)).

PMA is a rigorous process. Id. To obtain PMA, "a device manufacturer must submit to the FDA full reports of all investigations relating to the device's safety or effectiveness; a full statement of the components, ingredients, and properties and of the principle or principles of operation of the device, a full description of the manufacturing methods and the facilities and controls used for the device's manufacturing; references to any performance standards applicable to the device; samples of the device and any component parts; examples of the proposed labeling for the device; and other information as requested." Id. at 572–73 (citing 21 U.S.C. § 360e(c)(1)) (internal quotations omitted).

Given the extensive regulation of Class III medical devices and the preemption provision in the MDA, the Supreme Court has offered guidance on what claims survive the MDA's express preemption clause. In Riegel v. Medtronic, "the Supreme Court considered whether a plaintiff's common law claims based on the failure of a Class III medical device were precluded by the MDA's express preemption clause, which preempts state requirements 'different from, or in addition to' requirements applicable under federal law." Id. at 577 (citing Riegel v. Medtronic, 552 U.S. 312, 321 (2008)) (quoting 21 U.S.C. § 360k(a)(1)). To resolve this question, the court undertook a two-part inquiry. Riegal, 552 U.S. at 321–22. First, the Supreme Court examined whether the federal government established requirements applicable to the device. Id. at 321. The Supreme Court determined that, because Class III devices are required to undergo the PMA process, this first requirement is met in regard to all Class III

devices. Id. Second, the Supreme Court considered whether the state common law claims imposed requirements that were different from or in addition to the federal requirements and "relate[d] to the safety or effectiveness of the device or to any other matter included in a requirement of the device." Id. at 323.

"In sum, the Supreme Court held that the terms of a Class III device's [PMA] constitute federal requirements and that a common law tort claim premised on different or additional requirements is preempted by the MDA." Walker, 670 F.3d at 577. "The Supreme Court did recognize one situation in which a plaintiff's common law claims would not be preempted under the MDA: when 'state duties . . . parallel, rather than add to, federal requirements.'" Id. (quoting Riegel, 552 U.S. at 330) (internal quotation marks omitted). "This situation occurs when claims are 'premised on a violation of FDA regulations.'" Id. (quoting Riegel, 552 U.S. at 330). With this guidance in mind, the court turns to Feeser's claims in this case.

Feeser asserts three causes of action in his complaint: (1) negligence/gross negligence; (2) strict products liability; and (3) breach of warranty. The Supreme Court has held that state common law claims for negligence, strict liability, and breach of warranty, among other claims, qualify as "requirements . . . with respect to devices" for the purpose of the MDA's express preemption clause. Riegel, 552 U.S. at 324, 327. Thus, to determine whether these claims are preempted by the MDA, the court must decide whether they parallel federal requirements or impose requirements that differ from or add to those requirements. In so deciding, the court acknowledges that "[p]laintiffs cannot simply incant the magic words '[the defendant] violated FDA regulations' in order to avoid preemption." In re Medtronic, Inc. Sprint Fidelis Leads Prod. Liab. Litig., 592

F. Supp. 2d 1147, 1158 (D. Minn. 2009). District courts in the Fourth Circuit have unanimously held that a well-pleaded parallel state law claim "must at least (1) identify the federal requirement applicable to the device with which it allegedly failed to comply and (2) explain how that violation of a federal requirement caused the plaintiff's injury." See Wells v. Allergan USA, Inc., 2014 WL 117773 *2 (D.S.C. Jan. 13, 2014) (collecting cases); Ellis v. Smith & Nephew, Inc., 2016 WL 7319397, at *2 (D.S.C. Feb. 16, 2016)

The critical factual allegation underlying Feeser's three claims against Medtronic boils down to the following: "The device sent and tested for approval included a coating as an essential element of the device. The [subject Pacemaker] had no coating; therefore, it was not the same device or line of devices sent for FDA testing." ECF No. 7 at 3. The court finds that, through this allegation, Feeser sufficiently identifies the federal requirement that Medtronic allegedly violated. Viewing the complaint in the light most favorable to Feeser and accepting the allegations therein as true, Feeser has plausibly alleged that Medtronic failed to comply with the Pacemaker's specific PMA requirements. See Riegel, 552 U.S. at 322–23 (noting that premarket approval "imposes requirements under the MDA" because "the FDA requires a device that has received premarket approval to be made with almost no deviations from the specifications in its approval application" (internal quotation marks omitted)). Moreover, Feeser sufficiently explains how that alleged violation caused his injury. Specifically, Feeser alleges that the lack of the protective coating caused the Pacemaker to stop working such that he had to remove and replace it. At this stage, it remains to be seen whether Feeser can prove that

the Pacemaker's PMA documents require a protective coating,[1] that the Pacemaker he received did not have the protective coating, or that the alleged lack of coating was, in fact, the cause of his problems that necessitated removal and replacement. However, Feeser has pleaded enough facts to support a plausible inference that Medtronic violated the PMA and federal law by manufacturing the Pacemaker without a protective coating. Therefore, to the extent Feeser's claims are based on the lack of a protective coating, those claims do not differ from or add to federal requirements and are sufficiently parallel to fall outside the scope of MDA preemption. See Williams v. Smith & Nephew, Inc., 123 F. Supp. 3d 733, 744 (D. Md. 2015) ("[T]he bulk of the Williamses' claims assert that the BHR System was manufactured and distributed out of compliance with the terms of its PMA. That takes those claims outside the scope of section 360k's protections. (emphasis in original and footnote omitted)); Hill v. Abbott Lab'ys, 2020 WL 4820243, at *5 (D.S.C. Aug. 19, 2020) (holding that the plaintiff's claims for "negligence and manufacturing defects, which specifically contend[ed] that the St. Jude Defendants' conduct violated the PMA and federal law," were sufficient to survive a motion to dismiss and that the plaintiff "should have the opportunity to conduct discovery to determine what the PMA's requirements are and whether the St. Jude Defendants complied with those requirements."). However, to the extent Feeser's claims are based on any other defect in the design or manufacture of the Pacemaker, the court dismisses those claims as preempted. For example, Feeser broadly complains that the design

[1] Because PMA files are generally confidential, without discovery, they are likely accessible only to Medtronic and to the FDA and are not before the court. However, at the motion to dismiss stage, Feeser need only plausibly allege—not prove—that the terms of the PMA require such a coating.

"fail[ed] to eliminate all hazards" and did not "meet[] applicable safety requirements." Compl. at 7. Because Medtronic's design of the Pacemaker was approved through the PMA process, any allegations challenging that design attempt to add to or differ from federal requirements and are accordingly preempted. See Walker, 670 F.3d at 580 ("A common law tort claim that presupposes a Class III device should have been designed in a manner other than that contemplated by its premarket approval is therefore expressly preempted by the MDA as interpreted by Riegel."). And the only specific allegations in the complaint that Medtronic deviated from the PMA-approved design relate to the protective coating. Therefore, this is the only ground underlying Feeser's claims on which he may proceed. See Wells, 2014 WL 117773, at *3 (D.S.C. Jan. 13, 2014) (finding claims were not parallel where "the Amended Complaint d[id] not identify specific device defects or violations of any specific PMA terms"). Medtronic will have its opportunity to challenge these factual allegations on a motion for summary judgment after the parties have had an opportunity to conduct discovery regarding the actual device that was implanted in Feeser and the PMA requirements with which the device was required to comply.

B. Factual Allegations

Alternatively, Medtronic argues that, even if Feeser's claims were not preempted, Feeser fails to state a claim for any of his three causes of actions because he does not (1) identify the subject pacemaker, (2) plead sufficient facts to support his claims, or (3) plead that a reasonable alternative design exists to support the design-defect allegations underlying the claims. The court finds that none of these arguments warrant dismissal of Feeser's claims that are not barred by the MDA preemption clause.

Medtronic insists that Feeser has failed to properly identify the Pacemaker at issue. Medtronic explains that Feeser alleges that the subject Pacemaker was recalled due to a lack of a specific coating, polytetrafluoroethylene ("PTFE"). However, according to Medtronic, the Pacemaker Feeser identifies by model number and serial number does not include a protective coating made of PTFE by design and was not recalled for coating issues. Therefore, Medtronic argues that the Pacemaker is not properly identified, and, accordingly, Medtronic cannot defend itself against Feeser's claims. The court finds that this challenge is not properly brought on a motion to dismiss. On such a motion, the court must accept all well-pleaded allegations as true and view the complaint in the light most favorable to Feeser. Although Medtronic states that Feeser fails to specifically identify the Pacemaker, Feeser identifies the Pacemaker as the Azure™ S DR MRI SureScan™ Model W3DR01, serial number RNJ201863H. At bottom, Medtronic is challenging the veracity of the identification Feeser provides. Without evidence on the issue, the court cannot consider whether the Pacemaker Feeser identifies was, in fact, the device that was implanted in him, whether PMA approval of the design of that device included a PTFE coating, or whether that device was recalled for failure to have that coating. Again, the parties may properly provide such evidence on summary judgment.

Next, Medtronic argues that Feeser fails to plead sufficient facts to support the elements of his negligence, strict products liability, and breach of warranty claims. The court need not engage in a lengthy discussion of the elements of each because Medtronic challenges all three causes of action for the same general reasons, and those reasons do not hold water. Specifically, Medtronic argues that all three causes of action require Feeser to identify the product that allegedly harmed him and to explain the harm or injury

that he experienced with specificity. Medtronic contends that Feeser fails to do. Additionally, Medtronic argues that Feeser fails to provide facts to show how the Pacemaker was "unreasonably dangerous" to support his strict product liability claim or why it was "not merchantable at the time of sale" to support his breach of implied warranty of merchantability claim. ECF No. 5 at 16. According to Medtronic, these deficiencies warrant dismissal of the complaint.

The court disagrees. As explained above, Feeser sufficiently identifies the Pacemaker at issue. Likewise, Feeser sufficiently alleges that the Pacemaker was unreasonably dangerous, not merchantable,[2] and not fit for its intended purpose[3] because he alleges it lacked the protective coating that was approved during the PMA process and it did not function properly as a result. The cases Medtronic cites to support its position are inapposite because the plaintiffs in those cases, unlike Feeser, failed to specifically identify the product defect of which they complained. See, e.g., Funk v. Stryker Corp.,

[2] Goods are "merchantable" if they are "fit for the ordinary purposes for which such goods are used." Grubbs v. Wal-Mart Stores, Inc., 514 F. Supp. 3d 820, 824 (D.S.C. 2021).

[3] Medtronic contends that Feeser also fails to identify the warranties that existed, express or implied. This contention is without merit, as both the implied warranty of merchantability and the implied warranty of fitness for particular purpose are both explicitly identified in the complaint. Feeser appears to base his argument on a Fifth Circuit case where the plaintiff alleged that the product at issue "failed to comply with the 10 and 11 year warranty that was provided to [him] through his physicians, and medical providers, and by Medtronic, Inc. and its employees, agents and representative, and business affiliates." Naquin v. Medtronic, Inc., 2021 WL 4848838, at *3 (5th Cir. Oct. 18, 2021). The Fifth Circuit found that "[t]he pleadings failed to identity when, where, or how Medtronic made the alleged warranty" and therefore dismissed that claim based on Fifth Circuit precedent. Id. This case has no application to Feeser's implied warranty claims. Feeser points to no requirement under Fourth Circuit precedent or otherwise that a plaintiff must identify when, where, and how a merchant made an implied warranty of merchantability or fitness for a particular purpose, and therefore the court will not dismiss those claims on that basis.

631 F.3d 777, 782 (5th Cir. 2011) ("This complaint is impermissibly conclusory and vague; it does not specify the manufacturing defect . . . ."); Naquin, 2021 WL 4848838, at *3 ("[N]owhere does Naquin provide details as to how a violation of federal regulations produced a manufacturing or design defect or how a specific defect caused his alleged harms."). Finally, Feeser sufficiently alleges the harm he suffered—namely, that he had complications with the Pacemaker and had to undergo a second surgery to have it removed and replaced. Accordingly, Medtronic's contentions that Feeser does not allege sufficient factual matter to support his claims all fail.

As a final ground for dismissal, Medtronic also argues that Feeser fails to plead the existence of a reasonable alternative design to support the design-defect allegations underlying all three of his claims. However, the court has already dismissed, as preempted by the MDA, any claims based on the Pacemaker's PMA-approved design, and therefore, Medtronic's argument is moot as to those claims. Moreover, Feeser clearly alleges a reasonable alternative design to the extent he challenges the "design" of the Pacemaker he received as allegedly omitting the PMA-required protective coating. Of course, the alleged reasonable alternative design is one with the requisite coating. Accordingly, the court does not find Feeser's factual pleadings inadequate, and the motion to dismiss is denied in part in this respect.

IV. CONCLUSION

For the reasons set forth above, the court **GRANTS IN PART AND DENIES IN PART** the motion to dismiss in accordance with this order.

AND IT IS SO ORDERED.

DAVID C. NORTON
UNITED STATES DISTRICT JUDGE

February 8, 2022
Charleston, South Carolina